

WE CLAIM

1. A method for diagnosing a cancer in a mammal, comprising:
 - a) determining NMB gene copy number in a test sample from a region of the mammal that is suspected to be precancerous or cancerous, thereby generating data for a test gene copy number; and
 - b) comparing the test gene copy number to data for a control gene copy number, wherein an amplification of the gene in the test sample relative to the control indicates the presence of a precancerous lesion or a cancer in the mammal.
2. The method according to claim 1, wherein the control gene copy number is two copies per cell.
3. The method according to claim 1, wherein the cancer is a breast cancer, a colon cancer, a lung cancer, a brain cancer, or an ovarian cancer.
4. A method for inhibiting cancer or precancerous growth in a mammalian tissue, comprising contacting the tissue with an inhibitor that interacts with NMB DNA or RNA and thereby inhibits NMB gene function.
5. The method according to claim 4, wherein the tissue is a breast tissue, a colon tissue, a lung tissue, a brain tissue, or an ovarian tissue.
6. The method according to claim 4, wherein the inhibitor is a siRNA, miRNA, an antisense RNA, an antisense DNA, a decoy molecule, or a decoy DNA.
7. The method according to claim 4, wherein the inhibitor contains nucleotides, and wherein the inhibitor comprises less than about 100 bps in length.
8. The method according to claim 4, wherein the inhibitor is a ribozyme.
9. The method according to claim 4, wherein the inhibitor is a small molecule.
10. A method for inhibiting cancer or precancerous growth in a mammalian tissue, comprising contacting the tissue with an inhibitor of NMB protein.
11. The method according to claim 10, wherein the tissue is a breast tissue, a colon tissue, a lung tissue, a brain tissue, or an ovarian tissue.
12. A method for diagnosing a cancer in a mammal, comprising:

- a) determining the level of NMB in a test sample from a region of the mammal that is suspected to be precancerous or cancerous, thereby generating data for a test level; and
- b) comparing the test level to data for a control level, wherein an elevated test level of the test sample relative to the control level indicates the presence of a precancerous lesion or a cancer in the mammal.

13. The method according to claim 12, wherein the control level is obtained from a database of NMB levels detected in a control sample.

14. A method of administering siRNA to a patient in need thereof, wherein the siRNA molecule is delivered in the form of a naked oligonucleotide or a vector, wherein the siRNA interacts with NMB gene or NMB mRNA transcript.

15. The method of claim 14, wherein the siRNA is delivered as a vector, wherein the vector is a plasmid, cosmid, bacteriophage, or a virus.

16. The method of claim 14, wherein the vector is a retrovirus or an adenovirus based vector.

17. A method of blocking *in vivo* expression of a gene by administering a vector encoding NMB siRNA.

18. The method of claim 17, wherein the siRNA interferes with NMB activity.

19. The method of claim 17, wherein the siRNA causes post-transcriptional silencing of NMB gene in a mammalian cell.

20. The method of claim 19, wherein the cell is a human cell.

21. A method of screening a test molecule for NMB antagonist activity comprising the steps of:

- a) contacting the molecule with a cancer cell;
- b) determining the level of NMB in the cell, thereby generating data for a test level; and
- c) comparing the test level to the NMB level of the cancer cell prior to contacting the test molecule, wherein a decrease in NMB in the test level indicates NMB antagonist activity of the test molecule.

22. The method of claim 21, wherein the level of NMB is determined by reverse transcription and polymerase chain reaction (RT-PCR).

23. The method of claim 21, wherein the level of NMB is determined by Northern hybridization.

5 24. The method of claim 21, wherein the cell is obtained from a breast tissue, a colon tissue, a lung tissue, a brain tissue, or an ovarian tissue.

25. A method of screening a test molecule for NMB antagonist activity comprising the steps of:

a) contacting the molecule with NMB; and

10 b) determining the effect of the test molecule on NMB.

26. The method according to claim 25, wherein the effect is determined via a binding assay.

27. A method of determining whether a test molecule has NMB antagonist activity, wherein the method comprises:

a) determining the level of NMB in a test sample containing cancer cells, thereby
15 generating data for a control level;

b) contacting the molecule with the test sample to generate data for a test level; and

c) comparing the control level to the test level, wherein no decrease in NMB in the
test level as compared to the control level indicates that the test molecule has no
NMB antagonist activity.

20 28. A method for selecting test molecules having NMB antagonist activity, wherein the method comprises:

a) determining the level of NMB in a test sample containing cancer cells, thereby
generating data for a control level;

b) contacting the molecule with the test sample to generate data for a test level;

25 c) comparing the control level to test level, wherein no decrease in NMB in the test
level as compared to the control level indicates that the test molecule has no NMB
antagonist activity; and

d) eliminating the test molecule from further evaluation or study.

29. A method for determining the efficacy of a therapeutic treatment regimen in a patient, comprising:

- a) measuring the NMB gene copy number in a first sample obtained from a patient, thereby generating an initial level;
- b) administering the treatment regimen to the patient;
- c) measuring the NMB gene copy number in a second sample from the patient at a time following administration of the treatment regimen, thereby generating a test level; and
- d) comparing the initial and test levels, wherein a decrease in the gene copy number level in the test level relative to the initial level indicates that the treatment regimen is effective in the patient.

30. The method according to claim 29, wherein the sample is obtained from a breast tissue, a colon tissue, a lung tissue, a brain tissue, or an ovarian tissue.

31. A method for determining the efficacy of a therapeutic treatment regimen in a patient, comprising:

- a) measuring at least one of NMB mRNA or NMB expression levels in a first sample obtained from the patient, thereby generating data for a pre-treatment level;
- b) administering the treatment regimen to the patient;
- c) measuring at least one of NMB mRNA or NMB expression levels in a second sample from the patient at a time following administration of the treatment regimen, thereby generating data for a test level; and
- d) comparing the pre-treatment level to the test level, wherein data showing no decrease in the test level relative to the pre-treatment level indicates that the treatment regimen is not effective in the patient.

32. A method for selecting test molecules having a therapeutic effect in a patient, comprising:

- a) measuring at least one of NMB mRNA or NMB expression levels in a first sample obtained from the patient, thereby generating data for a pre-treatment level;

- b) administering the test molecule to the patient;
 - c) measuring at least one of NMB mRNA or NMB expression levels in a second sample from the patient at a time following administration of the test molecule, thereby generating data for a test level;
 - 5 d) comparing the pre-treatment level to the test level, wherein data showing no decrease in the test level relative to the pre-treatment level indicates that the test molecule is not effective in the patient; and
 - e) eliminating the test molecule from further evaluation or study.
33. A method for diagnosing a cancer in a mammal, comprising:
- 10 a) determining NMBR gene copy number in a test sample from a region of the mammal that is suspected to be precancerous or cancerous, thereby generating data for a test gene copy number; and
 - b) comparing the test gene copy number to data for a control gene copy number, wherein an amplification of the gene in the test sample relative to the control
15 indicates the presence of a precancerous lesion or a cancer in the mammal.
34. The method according to claim 33, wherein the control gene copy number is two copies per cell.
35. The method according to claim 33, wherein the cancer is a breast cancer, a colon cancer, a lung cancer, a brain cancer, or an ovarian cancer.
- 20 36. A method for inhibiting cancer or precancerous growth in a mammalian tissue, comprising contacting the tissue with an inhibitor that interacts with NMBR DNA or RNA and thereby inhibits NMBR gene function.
37. The method according to claim 36, wherein the tissue is a colon tissue, an ovarian tissue, or a breast tissue.
- 25 38. The method according to claim 36, wherein the inhibitor is a siRNA, miRNA, an antisense RNA, an antisense DNA, a decoy molecule, or a decoy DNA.
39. The method according to claim 36, wherein the inhibitor contains nucleotides, and wherein the inhibitor comprises less than about 100 bps in length.
40. The method according to claim 36, wherein the inhibitor is a ribozyme.

41. The method according to claim 36, wherein the inhibitor is a small molecule.
42. A method for inhibiting cancer or precancerous growth in a mammalian tissue, comprising contacting the tissue with an inhibitor of NMBR protein.
43. The method according to claim 42, wherein the tissue is a breast tissue, a colon tissue, a lung tissue, a brain tissue, or an ovarian tissue.
44. A method for diagnosing a cancer in a mammal, comprising:
- a) determining the level of NMBR in a test sample from a region of the mammal that is suspected to be precancerous or cancerous, thereby generating data for a test level; and
 - b) comparing the test level to data for a control level, wherein an elevated test level of the test sample relative to the control level indicates the presence of a precancerous lesion or a cancer in the mammal.
45. The method according to claim 44, wherein the control level is obtained from a database of NMBR levels detected in a control sample.
46. A method of administering siRNA to a patient in need thereof, wherein the siRNA molecule is delivered in the form of a naked oligonucleotide or a vector, wherein the siRNA interacts with NMBR gene or NMBR mRNA transcript.
47. The method of claim 46, wherein the siRNA is delivered as a vector, wherein the vector is a plasmid, cosmid, bacteriophage, or a virus.
48. The method of claim 46, wherein the vector is a retrovirus or an adenovirus based vector.
49. A method of blocking *in vivo* expression of a gene by administering a vector encoding NMBR siRNA.
50. The method of claim 49, wherein the siRNA interferes with NMBR activity.
51. The method of claim 49, wherein the siRNA causes post-transcriptional silencing of NMBR gene in a mammalian cell.
52. The method of claim 51, wherein the cell is a human cell.
53. A method of screening a test molecule for NMBR antagonist activity comprising the steps of:
- a) contacting the molecule with a cancer cell;

- b) determining the level of NMBR in the cell, thereby generating data for a test level; and
- c) comparing the test level to the NMBR level of the cancer cell prior to contacting the test molecule, wherein a decrease in NMBR in the test level indicates NMBR antagonist activity of the test molecule.

54. The method of claim 53, wherein the level of NMBR is determined by reverse transcription and polymerase chain reaction (RT-PCR).

55. The method of claim 53, wherein the level of NMBR is determined by Northern hybridization.

56. The method of claim 53, wherein the cell is obtained from a breast tissue, a colon tissue, a lung tissue, a brain tissue, or an ovarian tissue.

57. A method of screening a test molecule for NMBR antagonist activity comprising the steps of:

- a) contacting the molecule with NMBR; and
- b) determining the effect of the test molecule on NMBR.

58. The method according to claim 57, wherein the effect is determined via a binding assay.

59. A method of determining whether a test molecule has NMBR antagonist activity, wherein the method comprises:

- a) determining the level of NMBR in a test sample containing cancer cells, thereby generating data for an initial level;
- b) contacting the molecule with the test sample to generate data for a test level; and
- c) comparing the initial level to the test level, wherein no decrease in NMBR in the test level as compared to the initial level indicates that the test molecule has no NMBR antagonist activity.

60. A method for selecting test molecules having NMBR antagonist activity, wherein the method comprises:

- a) determining the level of NMBR in a test sample containing cancer cells, thereby generating data for an initial level;
- b) contacting the molecule with the test sample to generate data for a test level;

- c) comparing the initial level to test level, wherein no decrease in NMBR in the test level as compared to the initial level indicates that the test molecule has no NMBR antagonist activity; and
- d) eliminating the test molecule from further evaluation or study.

5 61. A method for determining the efficacy of a therapeutic treatment regimen in a patient, comprising:

- a) measuring the NMBR gene copy number in a first sample obtained from a patient, thereby generating an initial level;
- b) administering the treatment regimen to the patient;
- 10 c) measuring the NMBR gene copy number in a second sample from the patient at a time following administration of the treatment regimen, thereby generating a test level; and
- d) comparing the initial and test levels, wherein a decrease in the gene copy number level in the test level relative to the initial level indicates that the treatment
15 regimen is effective in the patient.

62. The method according to claim 61, wherein the sample is obtained from a colon tissue, an ovarian tissue, or a breast tissue, a colon tissue, a lung tissue, a brain tissue, or an ovarian tissue.

20 63. A method for determining the efficacy of a therapeutic treatment regimen in a patient, comprising:

- a) measuring at least one of NMBR mRNA or NMBR expression levels in a first sample obtained from the patient, thereby generating data for a pre-treatment level;
- b) administering the treatment regimen to the patient;
- 25 c) measuring at least one of NMBR mRNA or NMBR expression levels in a second sample from the patient at a time following administration of the treatment regimen, thereby generating data for a test level; and

- d) comparing the pre-treatment level to the test level, wherein data showing no decrease in the test level relative to the pre-treatment level indicates that the treatment regimen is not effective in the patient.

64. A method for selecting test molecules having a therapeutic effect in a patient, comprising:

- a) measuring at least one of NMBR mRNA or NMBR expression levels in a first sample obtained from the patient, thereby generating data for a pre-treatment level;
- b) administering the test molecule to the patient;
- c) measuring at least one of NMBR mRNA or NMBR expression levels in a second sample from the patient at a time following administration of the test molecule, thereby generating data for a test level;
- d) comparing the pre-treatment level to the test level, wherein data showing no decrease in the test level relative to the pre-treatment level indicates that the test molecule is not effective in the patient; and
- e) eliminating the test molecule from further evaluation or study.